

110117400/BLN

CLAIMS

1. A method of determining prothrombin time (PT) in a whole blood, anti-coagulated blood,
5 blood plasma or anti-coagulated blood plasma sample comprising the steps of
a) adding a defined volume of the sample to a defined volume of a liquid reagent, or vice
versa, in a vessel,
b) determining the temperature of the reaction mixture of a) at an ambient
temperature in the range of 15°C to 45°C,
10 the steps a) and b) being performed in an optional order, followed by
c) determining a clotting time (CT) by registering the time from the addition in a) until a clot is
detected in the vessel,
and
d) calculating the prothrombin time (PT) based on the temperature of b) and the clotting
15 time (CT) of c).
2. The method according to claim 1, wherein the liquid reagent comprises two or three
different reagents.
- 20 3. The method according to claim 1 or 2, wherein the liquid reagent contains an amount of
fibrinogen increasing the concentration of fibrinogen in the mixture of a) by at least 0.1 g/L
and the ratio between the defined volume of the reagent and sample in a) is at least four.
4. The method according to any one of claims 1 - 3, wherein the calculated prothrombin time
25 (PT) is expressed as International Normalized Ratio (INR).
5. The method according to any one of claims 1 - 4, wherein the determination of the
temperature in b) is accomplished by determining the ambient room temperature, provided
that the liquid reagent is of the same temperature.
30
6. The method according to any one of claims 1 to 5, wherein the ambient temperature is in
the range of 18°C to 35°C.
7. The method according to claim 6, wherein the ambient temperature is in the range of
35 30°C to 35°C.

8. The method according to claim 4, wherein the International Normalized Ratio (INR) of the sample is calculated using the equation

$$\text{INR} = (\text{CT}/(\text{NCT}(t)))^{\text{ISI}(t)}$$

5

wherein

CT = the clotting time of e) in claim 1,

t = the temperature of c) in claim 1,

NCT(t) = Normal Clotting Time (NCT) expressed as a function of the temperature t, and

10 ISI(t) = International Sensitivity Index (ISI) expressed as a function of the temperature t.

9. The method according to any one of claims 1 to 8, wherein the prothrombin time (PT) is obtained from a table with rows and columns where one is for various clotting times, and the other is various temperatures, and the PT is found in the intersection of clotting time and temperature.

15

10. A test kit for performing an analysis according to the method of any one of claims 1 - 9 comprising temperature recoding means, and one or several separate sealed vessels containing reagents for clotting one or more defined volumes whole blood, anti-coagulated blood, blood plasma or anti-coagulated blood plasma sample.

20

11. The test kit according to claim 10, wherein a reagent in a vessel contains fibrinogen in an amount that yields a final fibrinogen concentration of at least 0.1 g/L in a vessel when mixed with a sample to be tested.

25

12. The test kit according to claim 10 or 11, wherein the reagents in the vessels are in lyophilized form for reconstitution with one or more defined volumes of liquid prior to use.

13. The test kit according to any one of claims 10 - 12, additionally comprising time registration means.

30

14. The test kit according to any one of claims 10 -13, additionally comprising volume determining means.

35
